

MADSEN Capella² and the OTOSuite Otoacoustic Emissions module

User Guide

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Version release date

2013-02-27

Technical support

Please contact your supplier.

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1 Device Description

MADSEN Capella² is a portable Otoacoustic Emission (OAE) device. You use the OTOSuite Otoacoustic Emissions module to operate Capella². Capella² cannot be used without OTOSuite software.

2 Intended Use

The intended use of MADSEN Capella² and the OTOSuite Otoacoustic Emissions module is for the screening and diagnosis of patients using otoacoustic emission techniques. Capella², used together with the Otoacoustic Emissions module, is intended for use as an aid in diagnosing hearing related disorders, and as a tool in the evaluation of conditions which affect otoacoustic emission responses to auditory stimuli.

Capella² can be used for patients of all ages. It is intended for use by trained personnel in a hospital, nursery, clinic, audiologist's office or other appropriate setting. The Otoacoustic Emissions research and diagnostic components may be used by investigators and students to evaluate the usability and effects of measured otoacoustic emissions.

3 Typographical conventions

The use of Warning, Caution and Note

For safety reasons and appropriate use of the device and/or software, the manual contains **Warnings**, **Cautions** and **Notes**. These headings are used as follows:

Warning • Indicates that there is risk of death or serious injury to the user or patient.

Caution • Indicates that there is a risk of injury to the user or patient or risk of damage to data or the device.

Note • Indicates that you should take special notice.

4 Unpacking

1. Unpack the device carefully.

When you unpack the device and accessories, it is a good idea to keep the packing material in which they were delivered. If you need to send the device in for service, the original packing material will protect against damage during transport, etc.

2. Visually inspect the equipment for possible damage.
If damage has occurred, do not put the device into operation. Contact your local distributor for assistance.
3. Check with the packing list to make sure that you have received all necessary parts and accessories. If your package is incomplete, contact your local distributor.

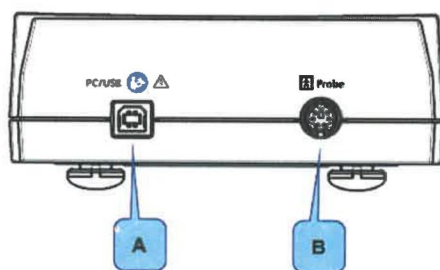
5 Assembling Capella

Caution • Install OTOSuite on the PC before you connect to MADSEN Capella² from the PC.

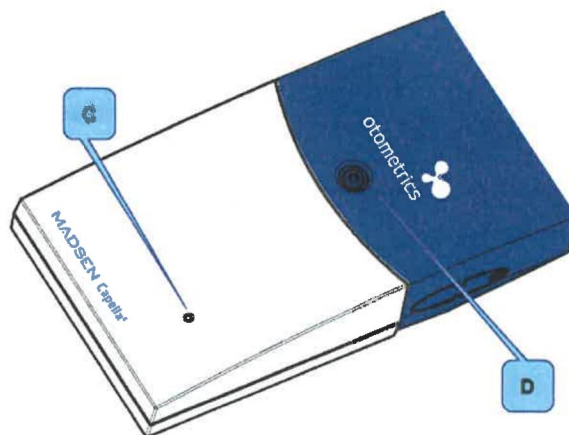
1. Ensure that OTOSuite has been installed on the PC.
For instructions on installing OTOSuite, see the OTOSuite Installation Guide, which is inserted in the OTOSuite installation disk box.
2. Shut down the PC.

Warning • The Capella² unit obtains power from the USB port. Make sure to connect the device while the computer is OFF, and then turn on the computer to install the hardware drivers.

Capella² is fully assembled on delivery. Once OTOSuite has been installed, you simply have to connect cables.



- A. USB Cable: Connection to computer
B. OAE Probe: 8-Pin mini DIN connector



- C. Power indicator
D. Probe test cavity

3. Connect the 10D OAE probe to Capella². Make sure that you only use probes provided with your system, the system is calibrated for exclusive use with the provided probe.
4. Insert one end of the USB cable in the USB port on Capella² and the other end in a USB port on the computer.
5. Power on the PC.

Switching off Capella²

To switch off Capella², disconnect the USB cable from the computer or switch off the computer.

5.1 10D OAE Probe



Warning • Do not connect this component to any other device.

Warning • Never connect the probe to a patient without an eartip.

To remove the probe tip:

- Using a small pointed object, such as a pen or small screwdriver, push in the notches on the left and right sides of the rear of the probe microphone casing until each tab is released.
- Slide the probe tip off the front of the probe and discard.

To replace the probe tip:

Caution • If the probe tip is not inserted completely and properly, the 10D probe will not function correctly.

1. Align a replacement tip with the front of the probe. The tip will only fit in one direction.
2. If the tip does not fit securely on the probe, remove the probe tip and reorient it.
3. Press lightly on the tabs to snap them into place. The tabs should be flush with the probe body.

5.2 Eartips

Eartips are used to provide a seal on the ear canal, preventing noise from affecting the stimulus, and creating a chamber for the stimulus to maintain a proper level.



Foam Eartips: OAE 14mm



Various Eartips: 04mm, 07mm and 09mm shown; for use with OAE Probe.



Pediatric Step-Up (yellow) ; for use with OAE Probe

Caution • Do not reuse.

Intact Skin Only

Eartips are to be used topically over intact skin only. Do not apply over infected skin.

Risk of Sensitivity

All eartips sold by Otometrics are made of hypo-allergenic material. These products do not contain latex.

Caution • Using the wrong size tip can lead to improper seal, resulting in noise issues or decreased stimulus sound levels while testing.

Warning • Never connect the probe to a patient without an eartip.

6 Preparing for testing

Ambient and Patient Noise

Minimize ambient noise. Cooperative patients can be instructed not to move or swallow during testing. Place the patient in a position that minimizes breathing noises.

Client State

In general it is best to test clients when they are sitting or lying down quietly.

Equipment Preparation

Clean all equipment components that have been in contact with other clients. Always use a new and clean eartip.

Turn on the equipment and start OTOSuite.

Warning • Turn on the equipment before inserting the probe in the patient's ear canal.

Warning • If there is any visible damage or the software detects a problem, do not attempt to test any patients until the problem has been fixed by the equipment manufacturer or by service personnel at an authorized workshop.

Ear Inspection

An otoscopic inspection of the external ear canal and tympanic membrane before probe fitting is recommended to determine whether a proper probe seal is possible. Debris and fluid inside the ear canal may prevent OAEs from being detected.

Warning • Do not clean the ear canal unless you are a certified audiologist or physician trained in this procedure. Severe injury and hearing loss may result to the client if the procedure is not done properly.

6.1 Placing the probe on the patient

A quality probe fit will optimize stimulus presentation and reduce ambient noise in the ear canal.

1. Place the eartip fully on the probe tip. Never connect the probe to a patient without an eartip.
2. Use the clip on the preamp box to attach the preamp box to clothing or bedding.
The position of the probe must remain stable throughout the recording to ensure proper testing.
3. Insert the probe firmly but gently into the ear canal.

Notes:

- Only individuals trained in these procedures should conduct the insertion of the eartip.
- It is important that hygienic precautions are taken to protect the client from cross-infection. Be sure to follow any established infection control procedures for the setting in which you are working.

- Do not clean the ear canal unless you are a certified audiologist or physician trained in this procedure. Severe injury and hearing loss may result to the client if the procedure is not done properly.
- Only appropriate eartips manufactured for the ER10D probe should be used.
- The tip should fit snugly in the ear canal to form a seal.
- The tip should not be loose or penetrate too deeply into the ear canal.

Fig. 1 10D - OAE Probe with foam ear tip



Warning • Eartips are not reusable.

7 Measuring Otoacoustic Emissions with Capella²

DPOAEs are responses generated by the cochlea to a two-tone stimulation presented to the ear. DPOAEs are generated by most normal healthy ears, and can be used to evaluate cochlear function. Each of the two applied stimulus pure tones is characterized by its frequency and sound intensity or level. The distortion products produced by the cochlea are a function of the two stimulation frequencies, denoted F1 and F2 and their two corresponding intensities or sound levels (L1 and L2). The largest distortion product occurs at a frequency that is two times F1 minus F2; $((2 * F1) - F2)$.

Distortion products are small in amplitude; to pick them up, Capella² uses a very sensitive microphone inside the ear probe. Due to the sensitivity of the recording microphone, ambient noise and noise generated by the patient such as talking, coughing and crying can hamper the detection of DPOAEs. A suitable testing environment and a proper probe fit are necessary for successful DPOAE measurements. Debris inside the ear canal may also hamper the recording of DPOAEs. Recording of DPOAEs are also affected by the physical state of the tympanic membrane and middle ear. An abnormal state of either of these elements (e.g., infection of the middle ear) can adversely affect the recording of DPOAEs.

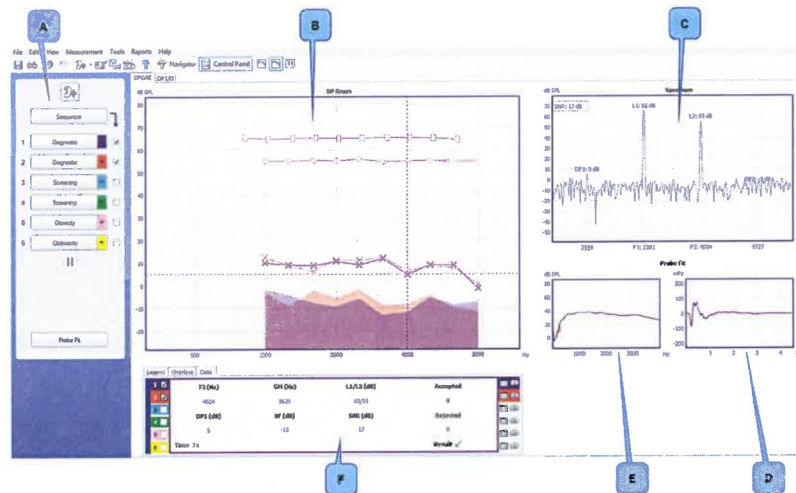
During acquisition, Capella² can test single or multiple DPOAE frequencies according to user specifications. The relationship between the two stimulation frequencies, the F2/F1 ratio, can be specified by selecting one frequency and the ratio and then allowing the system to calculate the second frequency value or by entering values for both F1 and F2 directly. The sound level of stimulation signals, L1 and L2, are also user selectable for each test conducted.

The DP I/O screen is used to record a patient's response to a specific frequency at different intensity levels.

7.1 The DP Otoacoustic Emissions Screens

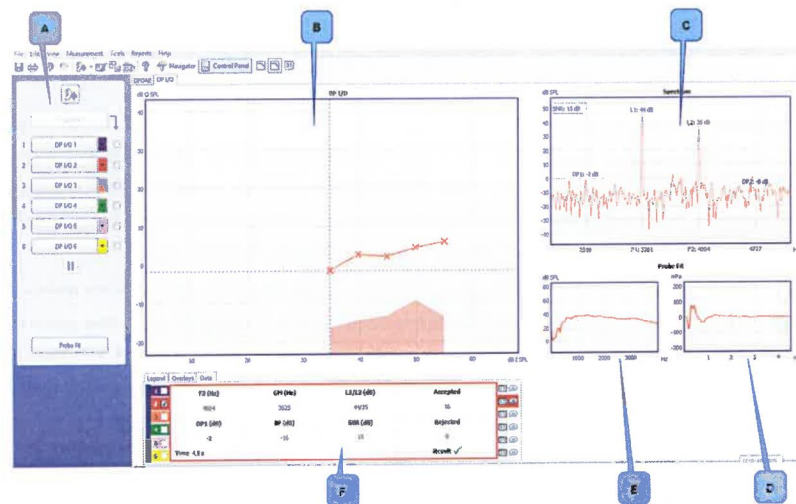
Both the DPOAE screen and the DP I/O screen contain the same basic elements:

DPOAE



- A. Control panel
- B. Result graph: DP Gram or DP I/O graph
- C. Spectrum graph
- D. Probe Fit- Time graph
- E. Probe Fit- Frequency graph
- F. Legend box/Overlays box/Data table

DPI/O



- A. Control panel
- B. Result graph: DP Gram or DP I/O graph
- C. Spectrum graph
- D. Probe Fit- Time graph
- E. Probe Fit- Frequency graph
- F. Legend box/Overlays box/Data table

7.2 Otoacoustic Emissions Control Panel

The control panel contains six measurement buttons that you can configure for different test protocols.

In **DPOAE**, you can set the intensity levels of F1 and F2, the frequencies to be tested and the sweep direction.

Note • F2 minimum and maximum values must be between 500 and 10,000 Hz. If you enter a value that is out of range, an error symbol will be displayed: ✖ (Simple Frequency Selection) or * (PrecisePoints Setup). If you close the dialog box while the error symbol is displayed, your changes will not be saved.

In **DP I/O**, you can set the frequency of F2 and the range of levels to be tested, the difference between L1 and L2, the interval between test levels, and the sweep direction.

Note • All test levels must be between 15 and 75 dB. If, for example, you enter 20 in the **Minimum (L1)** field and you enter -10 in the **Relative to L1** field, a message will appear at the bottom of the dialog box stating that a level is out of range, because the settings would cause L2 to play at 10 dB, which is out of range. Also, **OTOsuite** allows you to measure a maximum of 20 levels. If you enter a step size that will result in a larger number of levels, a message will be displayed in the dialog box.

✖ If you close the dialog box while the error symbol is displayed, your changes will not be saved.

For all buttons, you can edit the button title. You can also configure acceptance criteria for individual points and the overall test.

To access the configuration menus for a measurement button, click the drop-down button to the right of the measurement button.

7.3 The Results graph

The **DPOAE** test records the distortion products for fixed levels at different frequencies. The **DP I/O** test records the distortion products for fixed frequencies at different levels.

The results graph (**DP Gram** or **DP I/O graph**) displays the measured distortion product for each of the tested points.

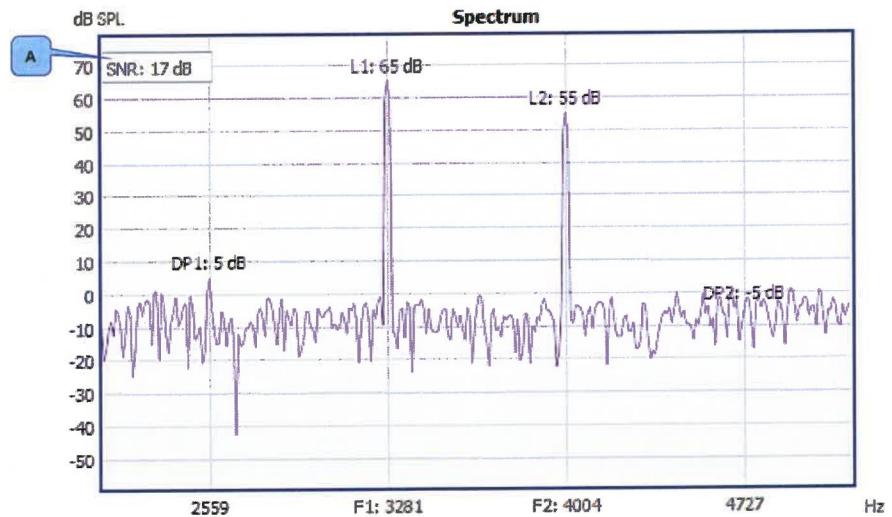
More than one measurement may be displayed in the results graph, depending on your selection in the **Legend** box. Other information such as the noise floor and standard deviation may be displayed, depending on the overlays that you select.

The distortion product response that is displayed in the results graph depends on the option that has been selected in the **Presented DP** field (**Options > Otoacoustic Emissions, View, Misc**). The default is to display **DP1** ($(2 \times F1) - F2$) for each frequency measurement, but it is also possible to select **DP2** ($(2 \times F2) - F1$).

7.4 The Spectrum graph

The Spectrum graph displays the results for the currently selected point on the DP Gram.

- A. Signal-to-Noise ratio of the selected DP



L1 and L2 are the measured levels of the pure tone primaries that were presented. The measured level may differ from the selected level if the probe was occluded or if the system was not properly calibrated or due to standing waves.

DP1 ($(2 \times F1) - F2$) and DP2 ($(2 \times F2) - F1$) are the resulting distortion products.

7.5 Probe Fit

At the beginning and end of each measurement, the Otoacoustic Emissions software checks the fit of the eartip and probe assembly in the ear. A 500 Hz tone is presented and the ear canal volume is checked. Based on this the software determines whether the probe is out of the ear, occluded, or OK. If the probe is not inserted correctly or if the probe is occluded, a dialog box is displayed. Adjust the probe and try again.

It may be impossible to achieve a good fit on certain patients. In those cases, reduce the external noise as much as possible and continue with the test. Results may be slightly compromised.

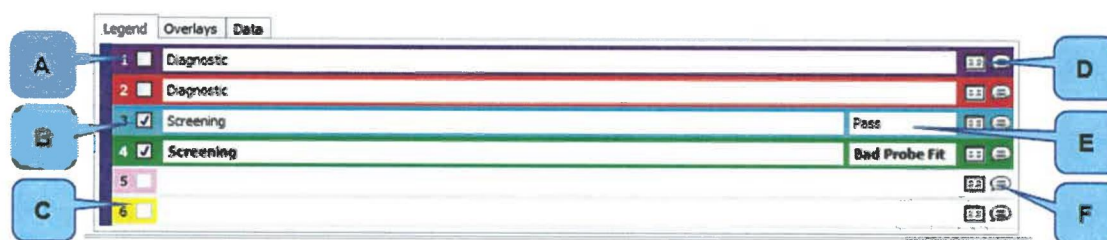
If the probe fit fails at the end of the measurement, you can choose to accept the measurement or to retry.

The Probe Fit graphs

The probe fit stimulus contains a click that is used to establish the meatal response. The **Probe Fit - Frequency** and **Probe Fit - Time** graphs display the measured response to the probe fit stimulation. These graphs are intended as a visual aid in assessing probe fit, or when comparing results from multiple measurements to ensure measurement conditions were similar for the compared curves.

7.6 The Legend box

You use the **Legend** box to select which measurements are displayed in the DP Gram. Each line in the Legend represents a measurement button and the corresponding curve that has been recorded.



- | | |
|---|--|
| A. Curve not displayed in graph | D. DP Gram Measurement Details button |
| B. Curve displayed in graph | E. Overall result |
| C. No measurement recorded for the button | F. Comment button |

If the test parameters for a measurement button include overall acceptance criteria, the overall result for the measurement will appear in the Legend box.

7.7 Overlays

The overlays in the DP Gram are all the same color as the measurement curve to which they correspond.

Normative Data	The normative data that is displayed depends on your selection in Options. Note • In order for the Normative Data overlay to be displayed, all curves displayed in the graph must be generated with the same L1 and L2 settings as were used to collect the applied normative data .
L1/L2	L1 and L2 are the measured levels of the pure tone primaries that were presented. □ indicates L1; ◇ indicates L2.
Two standard deviations above noise floor	You can display an overlay for one or two standard deviations above the noise floor to see how variable the noise floor is. This can be used as a kind of quality indicator of the measurement conditions for a given response curve. Large standard deviations may indicate poor or noisy measurement conditions. Small standard deviations suggest quiet conditions, which are likely to give more reliable results.
One standard deviation above noise floor	
Noise Floor	The noise floor is obtained by averaging 10 bins (spectral points) around the DP frequency.
Internal Noise	The initial average noise level measured with no stimulation.

7.8 Data table

The Data table presents the data for the currently selected point on the Results graph.

To view data for a point in the graph:

- Click on the point in the **DP Gram** or **DPI/O** graph. The cross hairs in the DP Gram indicate the current point. Data for the current point is displayed in the **Spectrum** graph and in the **Data** table.

The Data table

Legend	Overlays	Data
1 ☒		
2 ☐		
3 ☐		
4 ☐		
5 ☐		
6 ☐		

F2 (Hz)	GM (Hz)	L1/L2 (dB)	Accepted
625	566	65/55	24
DP1 (dB)	NF (dB)	SNR (dB)	Rejected
11	13	-2	0
Time 2,3 s			Result ✗

Contents of the Data table

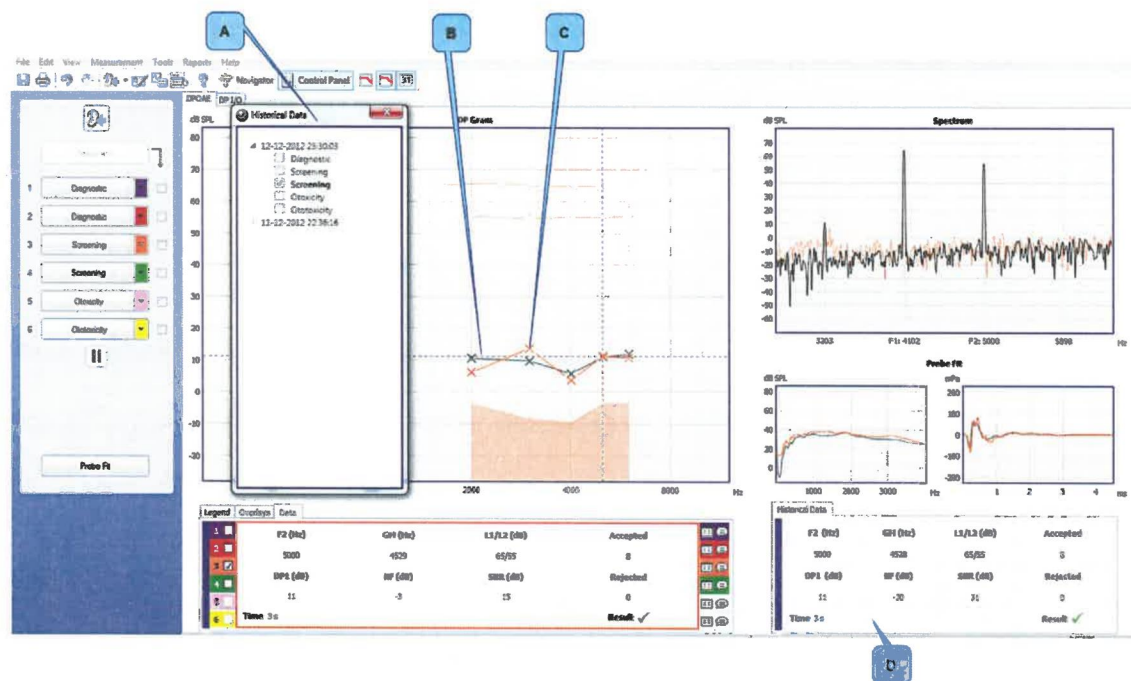
F2 (Hz) (or F1 (Hz))	The frequency at which the distortion product is plotted in the graph Depending on the selection in the DP Plot Position field in Options , either F1 or F2 will be displayed in the Data table. The default is F2 - the frequency of the second primary tone.
GM (Hz)	The Geometric Mean of the first and second primary tones ($\sqrt{F1 \times F2}$)
L1/L2 (dB)	Measured SPL level of the first and second primary tones presented
DP1 (dB) (or DP2 (dB))	The measured level of the distortion product plotted in the graph Depending on the selection in the Presented DP field in Options , either DP1 ($(2 \times F1) - F2$) or DP2 ($(2 \times F2) - F1$) will be displayed in the Data table. The default is DP1, which is typically the most robust Distortion Product.
NF (dB)	Noise floor
SNR (dB)	Signal to noise ratio (DP-NF) in dB
Accepted	Number of sweeps accepted, based on the Noise Reject Level field in Options (Options > Otoacoustic Emissions > General, Measurement > Common DP configuration). The number of Accepted and Rejected sweeps gives an indication of the quality of the measurement conditions.
Rejected	Number of sweeps rejected, based on the Noise Reject Level field in Options . The number of Accepted and Rejected sweeps gives an indication of the quality of the measurement conditions.
Time	The duration of all measurements at selected point
Result	Pass ✓ or Fail ✗ : Result for the point, according to acceptance criteria per point that has been set for the measurement.

7.9 Viewing historical data

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Capella² enables you to view data that is stored in NOAH from an earlier session. To view historical data, click the **Historical Data** icon in the toolbar. The **Historical Data** selection window opens and then you can select one or more curves

from earlier sessions. The selected historical curves are displayed in the **Results** graph, as well as the **Spectrum** graph and the **Probe Fit** graphs, for easy comparison to the current curve in the current session.



A. Historical Data selection window

B. Historical curve

C. New curve

D. Historical Data box

8 Service, Cleaning and Maintenance

Service

For the sake of safety and in order not to void the warranty, service and repair of electro-medical equipment should be carried out only by the equipment manufacturer or by service personnel at authorized workshops. In case of any defects, make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.

Warning • No modification of this equipment is allowed.

Cleaning

Use a soft, slightly damp cloth with a small amount of detergent to clean the device.

Caution • Follow your institution's procedures when cleaning the device. Do not use strong cleaners that may damage the plastic case. Do not allow any cleaning solution to get inside electronic components and connectors.

Maintenance

Capella² should be calibrated once a year by a service technician.

OTOSuite Software Upgrades

To obtain the latest version of OTOSuite, you can download the software from www.otometrics.com, or contact your local distributor.

9 Other references

For more information, see the online Help in OTOSuite, which contains detailed reference information about Capella² and Otoacoustic Emissions, and other OTOSuite products.

For instructions on installing OTOSuite, see the OTOSuite Installation Guide, which is inserted in the OTOSuite installation disk box.

10 Technical Specifications

Mode of Operation:	Continuous
Degree of Mobility	Portable Equipment
Expected Lifetime	10 Years from date of manufacture

10.1 Standards

Safety:	Class I (IEC 60601-1); Type BF, (IEC 60601-1); IPXO - Ordinary Equipment (IEC 60601-1)
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10.2 Operating environment

Temperature:	+15°C to +35°C (59°F to +95°F)
Relative humidity:	15% to 90% at 40°C non-condensing
Air pressure:	700 hPa to 1060 hPa

10.3 Storage environment

Temperature:	0°C to +50°C (32°F to +122°F)
Rel. humidity:	< 95%, non-condensing
Air pressure:	700 hPa to 1060 hPa

10.4 Electrical specifications

Rated Input Current:	0.5A
Rated Input Voltage:	+5V DC

10.5 PC power supply

The PC that Capella² is connected to should have a grounded power supply.

10.6 Technical specifications - 10D Probe

Connector	8-Pin mini DIN
Cable Length	6 feet (1.83 meters)
Net Weight	3.6 oz. (100 grams) approx.
Maximum Output	109 dB SPL - 64 dB SPL (frequency dependent)
Permissible Noise	40 dB SPL @ 2 kHz

10.7 Technical specifications - OAE Amplifier

The OAE amplifier, inside Capella², contains the low-pass filters, high-pass filters and gain settings used to acquire otoacoustic emission recordings from a 10D OAE probe, for OTOSuite.

General Specifications	
Frequency Range (DPOAE)	500 Hz - 10000 Hz
Frequency Accuracy	5% from selected
Measurement Accuracy	+/- 1dB SPL
Amplification (x1000)	100 DPOAE, 100 - 10,000 TEOAE

DPOAE Standard Acquisition Characteristics	
Sampling Rate	40064 Hz (Acquisition and Stimulation)
FFT Points	8192
FFT Resolution	4.89 Hz
Acquisition Time	204.27ms
Noise Calculation	Skips 2 bins then Measures 5 bins on each side of DP frequency: (DP-7, DP-6, DP-5, DP-4, DP-3, DP+3, DP+4, DP+5, DP+6, DP+7)

Hardware Components	
D/A Converter	LTC1609 (16 bit, +/- 5V)

Hardware Components	
A/D Converter	AD1866 (16 bit, +/- 5V)
Digital Attenuators	16 bit converters
Input	Microphone > Amplifier X100 Gain > A/D
Output	D/A > Driver > Speaker

10.8 Accessories

- 10D OAE Probe
- USB cable
- Wall Mount Kit (optional)

Disposable accessories

Item	Part number	Qty. in Starter Kit	Reorder Qty.
MADSEN Capella ² Starter Kit	8-69-42800		1
10D OAE Probe Cover Tips	1-12-73400	4	4
Probe cleaning tool	1-08-05300	1	1
Eartips - Plastic (See also Eartips ► 6)			
3-6 mm step up red	8-68-32300	4	100
4 mm yellow	8-68-32301	4	100
5 mm blue	8-68-32302	4	100
6 mm green	8-68-32303	4	100
7 mm yellow	8-68-32304	4	100
8 mm red	8-68-32305	4	100
9 mm blue	8-68-32306	4	100
10 mm green	8-68-32307	4	100
Eartips - Foam (See also Eartips ► 6)			
14 mm yellow	8-68-32308	4	50

11 Distributor

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9 Hoerskaetten, DK-2630 Taastrup
Denmark
☎ +45 45 75 55 55
📠 +45 45 75 55 59
www.otometrics.com

12 Manufacturer

Intelligent Hearing Systems
6860 SW 81st St.
Miami, FL 33143
USA



13 Responsibility of the manufacturer

GN Otometrics and the manufacturer, Intelligent Hearing Systems, are to be considered responsible for effects on safety, reliability, and performance of the equipment only if:

- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by the equipment manufacturer or personnel authorized by the manufacturer.
- The electrical installation to which the equipment is connected complies with EN/IEC requirements.
- The equipment is used in accordance with the instructions for use.

The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties.

14 Warning notes

This manual contains information and warnings, which must be followed to ensure the safe performance of the devices and software covered by this manual. Local government rules and regulations, if applicable, should also be followed at all times.

1. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
2. The System must be tested for leakage current by the biomedical engineering department of your institution.
The biomedical department of your institution must make sure that the leakage current test results comply with the

requirements of your region.

The system must be tested thoroughly before connecting any patients.

Computers connected to a network need to be tested for leakage current while connected to the network, a network connection may affect total leakage current.

3. Do not use the instrument in the presence of flammable anesthetics (gases).
4. The system is not protected against defibrillators. Remove patient connections before defibrillation. If defibrillation occurs, retest the system for leakage current to ensure safety.
5. Hazardous electrical output may occur. This equipment is for use by qualified personnel only.
The operator must not touch any of the electrical cables and the patient at the same time.
Patient connections are not intended for direct cardiac contact, although they are electrically isolated.
6. Read and follow the installation instructions in [Assembling Capella ► 5](#) when installing or transferring the system.
7. Only individuals who are trained in the use of the device and its principles should use MADSEN Capella². All results should be reviewed by a certified audiologist or licensed physician who has knowledge of Otoacoustic Emissions.
8. Do not clean the ear canal unless you are a certified audiologist or physician trained in this procedure. Severe injury and hearing loss may result to the client if the procedure is not done properly.
9. Only cables supplied by the distributor shall be used to connect the equipment to other parts or to external components as specified in the manuals.
10. It is important that hygienic precautions are taken to protect the client from cross-infection. Be sure to follow any established infection control procedures for the setting in which you are working.
11. No parts may be eaten, burnt, or in any way used for purposes other than the applications defined in the Intended Use section of this manual.
12. Keep the unit away from liquids. Do not allow moisture inside the unit.

Caution notes

1. Do not operate with damaged cords or plugs. Inspect all connection cords periodically for fraying or other damage.
2. When connecting all cables, do not force the connection; damage to the hardware may occur.
3. Read and follow the instructions provided in the user manual to ensure safe and proper use of the equipment.
4. When you connect other electrical equipment to MADSEN Capella², remember that equipment that does not comply with the same safety standards as MADSEN Capella² can lead to a general reduction in the system's safety level.
5. Turn off and disconnect all parts of the equipment when performing maintenance and cleaning.

15 Notes on EMC (Electromagnetic Compatibility)

- MADSEN Capella² is part of a medical electrical system and is thus subject to special safety precautions. For this reason, the installation and operating instructions provided in this document should be followed closely.
- Portable and mobile high-frequency communication devices, such as mobile phones, may interfere with the functioning of MADSEN Capella².

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
MADSEN Capella ² is intended for use in the electromagnetic environment specified below. The user of MADSEN Capella ² should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	MADSEN Capella ² uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. MADSEN Capella ² is suitable for use in all environments, including domestic environments and those directly connected to public low-voltage power supply networks that supply buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
MADSEN Capella ² is intended for use in the electromagnetic environment specified below. The user of MADSEN Capella ² should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note • U_i is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting			
MADSEN Capella ² is intended for use in the electromagnetic environment specified below. The user of MADSEN Capella ² should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of MADSEN Capella², including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{\frac{P}{f}}$ $d = 2.3 \sqrt{\frac{P}{f}}$ for 80 MHz to 800 MHz for 80 MHz to 2.5 GHz, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with this symbol: 
Note 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which MADSEN Capella² is used exceeds the applicable RF compliance level above, the MADSEN Capella² should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating MADSEN Capella². b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			
Recommended separation distances between portable and mobile RF communications equipment and MADSEN Capella ²			
The MADSEN Capella² is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MADSEN Capella² can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MADSEN Capella² as recommended below, according to the maximum output power of the communications equipment.			

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m	
	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

16 Definition of symbols

	Consult user manual for warnings and cautions.
	Follow instructions for use.
	Consult instructions for use.
	Complies with Medical Devices Directive 93/42/EEC.
	Complies with Type BF requirements of IEC60601-1.

	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste. You can return your device and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.
	Do not reuse.
	Used in error message dialogs if software program fails. See the detailed information in the dialog box.